

CERTIFICATE OF MAILING

I hereby certify that this paper and every paper referred to therein as being enclosed is being deposited with the U.S. Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on June 22, 1999 (Date of Deposit)



*Repl. / QB*

6/22/99 A. Bifullo  
Date Name

0646/0D205

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Ramesh A. BHAT et al.

Serial No: 08/906,365

Group Art Unit: 1646

Filed: August 5, 1997

Examiner: N. Basi

For: **NOVEL HUMAN ESTROGEN RECEPTOR-BETA**

June 22, 1999

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

**AMENDMENT**

Sir:

In response to the Office Action mailed December 22, 1998, and in accordance with Rule 115 of the Rules of Practice, please consider the following amendments and remarks. Also submitted is a Petition for Extension of Time for three (3) months, to and including June 22, 1999, accompanied by the required fee.

IN THE SPECIFICATION:

On page 12, line 9, after "codon" delete "in-fram" and insert therefor – in-frame –.

IN THE CLAIMS

Please cancel claims 19-23 without prejudice.

Please amend claims 1 and 9 as shown below:

1. (Amended) An isolated nucleic acid comprising the sequence depicted in Figure [1] 3, SEQ ID NO:1, wherein the sequence is flanked by heterologous sequences.

9. (Amended) A purified isolated nucleic acid encoding the amino acid sequence depicted in Figure [1] 4, SEQ ID NO:2, wherein a sequence of the nucleic acid encoding the amino acid sequence is flanked by heterologous sequences.

Please add the following new claims:

– 24. An isolated nucleic acid encoding an amino acid sequence corresponding to amino acids 1-45 of Figure 4, SEQ ID NO:2, wherein a sequence encoding the amino acid sequence is flanked by heterologous sequences.

25. A nucleic acid as defined in claim 24, wherein the sequence encoding the amino acid sequence has a nucleotide sequence corresponding to nucleotides 94-229 of Figure 3, SEQ ID NO:1.

26. A recombinant DNA vector comprising a sequence as defined in claim 24. –

REMARKS

Claims 1-18 and 24-26 are pending in the application. Claims 19-23 have been

canceled without prejudice as drawn to a non-elected invention, and Applicants reserve the right to prosecute these claims in a related divisional application. Claims 1 and 9 have been amended and new claims 24-26 have been added to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended recitation of claims 1 and 9 is found in the specification at page 16, line 22 to page 17, line 2, and at page 7, lines 14-16 (see also Figure 1; PCR primers that introduce restriction site linkers into the amplified sequence). New claims 24-26 are supported at page 3, lines 4-6 and page 16, lines 7-9, as well as described above for the amended recitation of claims 1 and 9.

The Specification has been amended to correct a typographical error.

**1. Restriction**

The Examiner has deemed the Requirement proper and has, therefore, made it FINAL. However, the Examiner has not withdrawn any claims from consideration.

Applicants have nevertheless canceled claims 19-23 without prejudice as drawn to a non-elected invention. With respect to claims 17 and 18, Applicants respectfully request reconsideration of the restriction requirement. As noted in the specification, and acknowledged by the Examiner, claims directed to the polypeptide having amino acid residues 1-45 as depicted in Figure 4 and SEQ ID NO:2, and correspondingly nucleic acids encoding such polypeptides, are novel and unobvious. No interest is served by maintaining the restriction requirement between Groups I and II when issues of patentability are capable of resolution by one examination. Applicants respectfully request that claims 17 and 18 be rejoined with claims 1-16 and 24-26.

## 2. Non-obviousness of the Invention

The Examiner has rejected claims 1, 2, 9, and 10 under 35 U.S.C. § 102(e) as being allegedly anticipated by Kausch, contending that the disclosure of Kausch meets the limitations of claims 1, 2, 9, and 10 because the host cell inherently contained the aforementioned nucleic acid molecules in the purified and isolated chromosomes.

The Examiner has similarly rejected claims 1, 2, 9, and 10 under 35 U.S.C. § 102(b) as being anticipated by Lin, contending that the disclosure of Lin meets the limitations of claims 1, 2, 9, and 10 because the host cell inherently contained the aforementioned nucleic molecules in the purified and isolated chromosomes shown in Figure 2.

In response, Applicants have amended claims 1 and 9 to recite that the nucleotide sequence recited in the claims is flanked by a heterologous sequence, *e.g.*, an artificial linker with restriction endonuclease sites to facilitate cloning, or by vector sequences after insertion in a cloning or expression vector. Examples of such heterologous sequences also include promoters, enhancers, response elements, signal sequences, polyadenylation sequences, introns, 5' and 3' non-coding regions, and the like (specification, page 16, line 22 to page 17, line 2).

Moreover, as presently claimed, an isolated purified nucleic acid of the invention is necessarily free of its original environment, *i.e.*, the chromosome. In this context, the present amendment merely clarifies an element found in the claims as filed by use of the term "isolated", which the specification defines as "... a nucleic acid ... that is removed from its original environment (for example, its natural environment if it is naturally occurring)" (page 15, lines 8-10).

In view of the foregoing amendment and remarks, Applicants submit that the Examiner's rejection is overcome and should be withdrawn.

3. Allowable Subject Matter

The Examiner has stated that claims 3-8 and 11-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In view of the foregoing amendments to claims 1 and 9, and the corresponding recitation in claim 24, it is believed that the basis for this objection is obviated.

CONCLUSION

In view of the above amendments and remarks, all of the pending claims are now believed to be in condition for allowance. However, should the Examiner find that outstanding issues remain, applicants respectfully request the Examiner to telephone the undersigned. Allowance of the claims is earnestly solicited.

Respectfully submitted,



Paul F. Fehlner, Ph.D.  
Reg. No. 35,135  
Attorney for Applicants

DARBY & DARBY PC  
805 Third Avenue  
New York, New York 10022  
212-527-7700